

Table 1. Pap Smear Cytology, Digene HPV DNA Hybrid Capture Assay Results, and Diagnosis or Status Regarding Dysplasia from Subjects Tested for Cervical Disease Via Enzyme-Linked Immunosorbent Assay (ELISA) Using Peptides Comprising Invention.

Subject Number	Pap Smear Interpretation <sup>1</sup>	Digene HPV Hybrid Capture <sup>2</sup>	Diagnosis or Status <sup>3</sup>
1	Not done	Not done	Virgin, 14 years old
2	Not done	Not done	Virgin, 15 years old
3	No cell abnormalities found	Negative	No history of dysplasia
4	No cell abnormalities found	Negative	No history of dysplasia
5	No cell abnormalities found	Negative	No history of dysplasia
6	No cell abnormalities found	Negative	No history of dysplasia
7	Cell abnormalities present	Negative	CIN I
8	No cell abnormalities found	Positive	CIN II
9	Cell abnormalities present	Positive	CIN II
10	Cell abnormalities present	Positive	CIN III
11	Cell abnormalities present	Positive	CIN III
12	Cell abnormalities present	Positive	CIN III
13	Cell abnormalities present	Positive	Squamous cell carcinoma
14	Cell abnormalities present	Positive	Squamous cell carcinoma
15	No cell abnormalities found	Positive	Adenocarcinoma
16	Cell abnormalities present	Positive	Adenocarcinoma

<sup>1</sup> ThinPrep slide interpreted by a Board Certified Cytopathologist

<sup>2</sup> DNA test for ascertaining presence/infection by “oncogenic” HPVs

<sup>3</sup> Where applicable, includes diagnosis or status after taking into account results from colposcopy and biopsy; CIN = Cervical Intraepithelial Neoplasia; CIN I = mild abnormalities that rarely develop into cervical cancer; CIN II = lesions appearing more aggressive under the microscope, involving about one-half of the thickness of the surface lining of the cervix; CIN III = the most aggressive form of dysplasia in which the entire surface lining is abnormal, high probability of progressing to invasive cancer if not removed and includes carcinoma in situ.

Table 2. Absorbance Values for Enzyme-Linked Immunosorbent Assays, or ELISAs, Using Peptides Comprising Invention. A reaction, oxidation of the bound enzyme-labeled antibody-antigen complex, produces a color for which intensity is proportional to the amount of antibody in the serum sample. Detection and quantification were done with absorbance at 450 nm, with values rounded to the nearest hundredths of absorbance units.

Subject Number	SEQUENCE ID NUMBER (SEQ ID NO:)							
	1	2	3	4	5	6	7	8
Blank Control	0.04	0.05	0.04	0.04	0.03	0.04	0.04	0.05
1	0.14	0.20	0.19	0.17	0.17	0.18	0.24	0.20
2	0.17	0.14	0.21	0.20	0.17	0.15	0.18	0.16
3	0.20	0.16	0.15	0.11	0.20	0.21	0.16	0.22
4	0.23	0.18	0.18	0.24	0.15	0.23	0.25	0.13
5	0.20	0.17	0.23	0.14	0.24	0.18	0.15	0.20
6	0.44	0.32	0.49	0.17	0.24	0.21	0.19	0.22
7	0.21	0.24	0.18	0.18	0.18	0.23	0.14	0.19
8	0.40	0.34	0.51	0.49	0.57	0.40	0.46	0.53
9	0.44	0.25	0.29	0.43	0.27	0.53	0.44	0.24
10	0.31	0.36	0.32	0.56	0.44	0.41	0.53	0.35
11	0.32	0.33	0.29	0.41	0.46	0.48	0.41	0.37
12	0.14	0.50	0.26	0.58	0.38	0.53	0.42	0.41
13	0.19	0.24	0.37	0.49	0.50	0.63	0.44	0.47
14	0.31	0.39	0.43	0.60	0.51	0.55	0.46	0.50
15	0.36	0.40	0.45	0.44	0.61	0.44	0.55	0.59
16	0.35	0.21	0.28	0.40	0.47	0.39	0.44	0.48

Kruskal--Wallis one-way analysis of variance on samples of unequal size:

Absorbance Values for Subjects 1-6 versus Absorbance Values for Subjects 7-16,  $p < 0.001$  (Extremely Significant)

Conclusion: Subjects with mild to severe cervical dysplasia and cancer have significantly greater antibody titers with respect to peptides of invention than do non-diseased or healthy subjects.

Fig. 2